52

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December 28, 2005

BY HAND DELIVERY

Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS-1502-FC (Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006)

Dear Administrator McClellan:

On behalf of a diverse group of organizations committed to assuring Medicare beneficiary access to lifesaving intravenous immune globulin (IVIG) therapies, we appreciate this opportunity to comment on the final rule with comment period concerning revisions to payment policies under the 2006 physician fee schedule that was published in the Federal Register on November 21, 2005 (Final Rule). 70 Fed. Reg. 70116. As a group of patient and provider organizations and industry participants, we are deeply committed to the health and safety of the Medicare beneficiaries who rely upon access to IVIG.

Throughout the fall, a group representing various sectors of the IVIG community has met in Washington, D.C. to discuss strategies for alleviating IVIG reimbursement problems experienced by Part B physicians and suppliers since the change in reimbursement methodology on January 1, 2005. This group includes representatives from patient advocacy organizations, including the Immune Deficiency Foundation (IDF), the Jeffrey Modell Foundation (JMF) and the Neuropathy Association (TNA); the medical community, including the American Academy of Allergy, Asthma and Immunology (AAAAI); health care group purchasing organizations, including Amerinet; distributors of IVIG represented by ASD Healthcare, Cardinal Health, FFF Enterprises, and the Specialty Pharma Distributors Association; and manufacturers of IVIG represented by the Plasma Protein Therapeutics Association and its member companies. The group represents over 80% of patients using IVIG, the manufacturers of over 80% of the plasma therapies for the United States (and more than 60% worldwide), the purchasers for more than 3,800 of our nation's hospitals, and the distributors of in excess of 80% of IVIG in the United States.

With regard to the Final Rule, these comments relate solely to the agency's treatment of IVIG furnished by physicians and suppliers and represent the views of the above groups. IVIG is the only effective treatment for primary immunodeficiency disease and

also has been proven clinically beneficial in the treatment of secondary immune deficiency diseases. In addition, individual United States licensed IVIG products are labeled for the treatment of: a) Kawasaki's disease; b) chronic lymphocytic leukemia or HIV infection during childhood to prevent bacterial infections; c) bone marrow transplantation to prevent graft versus host disease and bacterial infections in adults; and d) idiopathic thrombocytopenic purpura. Many individuals affected by diseases or conditions treated with IVIG depend on this life saving therapy for the rest of their lives. Each individual needs to have maximum access to the specific formulation which best meets their unique needs and does not pose serious or potentially life threatening complications.

The IVIG community is very appreciative of measures taken by the Centers for Medicare and Medicaid Services (CMS) to address the ongoing IVIG access situation. While we applaud the agency's recognition of the importance of ensuring that beneficiaries have access to IVIG and a need for additional payment for preadministration services related to IVIG, we do not believe that, given the drastic payment rate reductions applicable first to physicians and suppliers in 2005 and to hospital outpatient departments in 2006, CMS has exhausted all options within its authority to preserve access to IVIG. We have seen reduced access to IVIG through physicians and suppliers because of reimbursement concerns and we believe the same will be true in the hospital outpatient department going forward. That, unfortunately, will leave no alternate site of service such that patients may no longer able to obtain IVIG through a physician's office, a supplier, or a hospital outpatient department.

We urge CMS to take immediate action to ensure that payments to physicians and suppliers that furnish IVIG to beneficiaries are sufficient to ensure access as of January 1, 2006. We believe that the agency could do so by (i) establishing a comprehensive, permanent add-on payment to the rate for IVIG that captures the true acquisition, direct and indirect handling costs associated with IVIG; (ii) establishing unique Healthcare Common Procedure Coding System ("HCPCS") codes for each brand of IVIG so that the average sales price ("ASP") for each IVIG product is based on information submitted for that product and thus reflective of each product's unique formulation; and (iii) clarifying that IVIG is a biologic response modifier for purposes of paying for administering the product. These mechanisms are discussed separately below.

A. Add-On

In our comments on the 2006 physician fee schedule proposed rule, we advocated for an add-on payment for IVIG that captures the acquisition, direct and indirect handling costs associated with the product. Although the agency rejected a number of recommended payment adjustments for IVIG, including an add-on payment, because of its belief that ASP data are reflective of hospital acquisition costs for IVIG, it nonetheless determined that Medicare should make an additional payment of about $69 for each administration of IVIG to compensate for preadministration services related to IVIG. 70 Fed. Reg. at 70220.

The IVIG community appreciates the agency's recognition of these types of costs incurred in providing IVIG to beneficiaries, but believes that the additional preadministration payment is insufficient to ensure access to IVIG from physicians and suppliers, particularly in a year in which patients that migrated to hospital outpatient departments may experience less access in that setting and have to return to physicians and suppliers. While the additional payment does reimburse for some of the costs incurred related to IVIG, other costs would remain uncompensated. As we explained in our comment letter related to the proposed rule, the Plasma Protein Therapeutics Association (PPTA) and its member companies with the input of other stakeholders in the IVIG community, commissioned the Lewin Group to develop additional information to detail the costs incur related to IVIG. These data should help us identify the costs that remain uncompensated. Attached is a copy of the findings.

Moreover, we are concerned that the payment for preadministration services is labeled a temporary mechanism only for 2006. 70 Fed. Reg. at 70221. We envision that physicians and suppliers will continue to incur the costs that are compensated through this payment beyond 2006, and thus, it should be a permanent feature, augmented as suggested above to capture a fuller range of costs to furnish IVIG.

B. Expanded HCPCS Codes for IVIG Products

With payment for IVIG determined using the average sale price plus 6% payment methodology, we believe that CMS must take a critical step to ensure that this methodology establishes rates that are appropriate to sustain access to the various IVIG products as they are not interchangeable. Specifically, we believe that each brand name IVIG should have its own HCPCS code so that the ASP-based payment rate will be computed on its own ASP information, yielding rates that are pertinent to each brand, which should enhance access to IVIG products.

The following brands of intravenous immune globulin are now available in the United States market: Polygam® SD, Panglobulin® NF, Gammagard® S.D., Gamunex®, Flebogamma®, Octagam®, Carimune™ NF, and Gammagard® Liquid. Establishing a separate HCPCS codes for each brand is appropriate because there are important clinical differences among them, such as:

- Some brands contain no sugars, which is beneficial for diabetics;
- Some brands have low osmolality and low volume, which physicians sometimes prefer for patients with congestive heart failure or compromised renal function;
- Some brands contain sucrose, which can create a higher risk of renal failure;
- Some brands contain less immunoglobulin A ("IgA"), which is better for patients with IgA deficiencies; and
- Some brands have a lower pH, which may be preferable for patients with small peripheral vascular access or a tendency toward phlebitis.

Physicians prescribe different brands of IVIG due to these differences, yet CMS' coding and payment for these brands does not recognize such differences because there is just one code for liquid IVIG and one code for lyophilized (powder) IVIG. CMS can better assure the accuracy of the payment rates and thus promote access to all brands of IVIG by creating separate codes for each brand of IVIG. Brand specific reimbursement will serve another purpose of the agency as well – gaining an "improved understanding of the contemporary, volatile IVIG marketplace," 70 Fed. Reg. at 70220, by allowing CMS to track the individual brand name products.

According to the final rule the agency issued regarding the hospital outpatient prospective payment system, CMS considered establishing brand-specific HCPCS codes for IVIG, but did not find a "compelling" reason to override the standard practice of not establishing brand-specific codes. 70 Fed. Reg. 68516, 68648 (Nov. 10, 2005). The IVIG community respectfully believes that the Final Rule itself offers compelling reasons to override the standard practice, specifically:

- "we continue to be concerned about reports of patients experiencing difficulties in accessing timely IVIG treatments and reports of providers experiencing difficulties in obtaining adequate amounts of IVIG on a consistent basis to meet their patients' needs in the current marketplace." 70 Fed. Reg. at 70219;
- "The Secretary's Advisory Committee on Blood Safety and Availability has recommended immediate steps be taken to ensure access to IVIG so that patients' needs are being met." Id.;
- "the complexity of the IVIG marketplace makes it unclear what particular systematic approaches would be most effective in addressing the many individual circumstances that have been shared with us while not exacerbating what appears to be a temporary disruption in the marketplace." Id.;
- "Historically, numerous factors, including decreased manufacturer capacity, increased usage, more sophisticated processing steps, and low demand for byproducts from IVIG fractionation have affected the supply of IVIG." Id.;
- An additional payment for preadministration services is needed to "ensure that Medicare beneficiaries depending upon IVIG experience no adverse health consequences from the market instability for IVIG products." 70 Fed. Reg. at 70221; and
- "Based on the potential access concerns, the growing demand for IVIG, and the unique features of IVIG detailed above, as we seek to gain improved understanding of the contemporary volatile marketplace, we will employ a two-pronged approach during CY 2006 to help ensure the availability of IVIG to physicians and hospital outpatient departments." 70 Fed. Reg. at 70220.

We submit that the totality of these statements, in particular the decision to take a two-pronged approach to ensure continued access to IVIG across treatment settings, makes clear that there are compelling reasons to override the standard practice of not establishing brand-specific HCPCS codes. Accordingly, we urge CMS to issue brand-specific codes for IVIG products for use effective January 1, 2006.

C. IVIG Is a Biologic Response Modifier

CMS has incorporated the new Current Procedural Terminology ("CPT") codes to bill for drug administration services in 2006, as it indicated was likely in the proposed rule. Under these new codes, chemotherapy administration codes apply to "substances such as monoclonal antibody agents, and other biologic response modifiers."[1] As a result, when a physician administers a biologic response modifier, even though it may not be "chemotherapy," it is appropriate to bill 96413 for the administration service. The IVIG community urges CMS to clarify, in forthcoming instructions on billing for drug administration services or otherwise, that IVIG is a biologic response modifier and that physicians should bill for administering it under 96413 effective for services furnished on or after January 1, 2006.

Based on the above-quoted language in CPT 2006, any product that is a "biologic response modifier" should be billed under a chemotherapy administration code and IVIG is such a product. According to the U.S National Library of Medicine, biologic response modifier therapy is defined by reference to "immunotherapy," which is categorized as "Treatment to stimulate or restore the ability of the immune system to fight cancer, infections, and other diseases."[2] IVIG is precisely a treatment that restores the ability of the immune system to fight cancer and other diseases – e.g., Kawasaki's disease, chronic lymphocytic leukemia, primary immune deficiency disease, and secondary immune deficiency diseases. Accordingly, we urge CMS to provide written guidance indicating that IVIG is a biologic response modifier for purposes of billing for administering the product.

CONCLUSION

The group of organizations represented below appreciates the opportunity to comment on the Final Rule. We recognize and greatly appreciate CMS' effort and commitment to ensure patient access to IVIG and believe that further measures are needed in order to alleviate this ongoing situation. We are deeply concerned about the impact the Final Rule could have on beneficiary access to a life saving therapy, especially since there are limited other options as a site of care for patients dependent upon IVIG. In this comment letter, we offer three mechanisms to ensure that such beneficiaries will have continued access to IVIG through physicians and suppliers – a permanent and comprehensive add-on payment, establishment of brand-specific HCPCS codes, and recognition of IVIG as a biologic response modifier for purposes of drug administration billing. As explained above, there are ample reasons for CMS to take all three actions effective January 1, 2006.

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[1] CPT 2006 Current Procedural Terminology Professional Edition, at p. 400.
[2] *See* http://ghr.nlm.nih.gov/ghr/glossary/immunotherapy .

We look forward to continuing to work with CMS to ensure continued access to IVIG furnished by physicians and suppliers. Please contact Julie Birkofer at 202-789-3100 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,

Guillain-Barré Syndrome (GBS)/Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) Foundation International
Immune Deficiency Foundation (IDF)
Jeffrey Modell Foundation (JMF)
The Neuropathy Association (TNA)
Amerinet
American Academy of Allergy, Asthma and Immunology (AAAAI)
ASD Healthcare, AmerisourceBergen Specialty Group
Baxter BioScience
Cardinal Health
FFF Enterprises, Inc.
Grifols USA Inc.
Octapharma USA
The Plasma Protein Therapeutics Association
Talecris Biotherapeutics
ZLB Behring

AMA
AMERICAN MEDICAL ASSOCIATION

December 22, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-FC P.O. Box 8017
Baltimore, Maryland 21244-8017

Dear Doctor McClellan:

The American Medical Association/Specialty Society RVS Update Committee (RUC) appreciates the opportunity to comment on the Notice of *Final Rule* for the 2006 Physician Payment Schedule, published in the November 21, 2005 *Federal Register*.

Work Relative Values

The AMA/Specialty Society RVS Update Committee would like to thank the Centers for Medicare and Medicaid Services (CMS) for accepting 97 percent of the RUC recommended values, making budget neutrality adjustments to 10 codes. We commend CMS on implementing our work relative value recommendations for these services. We also acknowledge the valuable contributions of your staff in attending and observing our meetings. The RUC sincerely appreciates the confidence that CMS has displayed in our process. We also believe that our recommendations are based on quality data and serious deliberations. Therefore, we are offering additional comments on RUC recommendations that you have not accepted. We hope that this additional information is helpful to you in refining the relative values for the 2005 *Final Rule*. We also urge you to consider additional information that the specialty societies include in their comments.

Moderate Conscious Sedation

The RUC submitted work and practice expense recommendations on several new CPT 2006 codes describing the services of Moderate Conscious Sedation. CMS has stated that it is uncertain whether the RUC assigned values are appropriate and have carrier priced these codes in order to gather information for utilization and proper pricing. The RUC would be pleased to provide any further information to address your concerns. We hope to resolve these remaining issues with you and would be willing to schedule a discussion at the April 2006 RUC Meeting, after you have had a few months experience with the utilization of these codes.

Intraoperative Consult and Touch Prep

In the *Final Rule*, CMS has disagreed with the RUC approved work relative value unit (RVU) of 0.80 for new CPT code 88334, *Pathology consultation during surgery; cytologic examination (e.g., touch prep, squash prep), each additional site* and assigned a value 0.59 work RVUs providing the rationale that although 88334 has an additional five minutes of intra-service time and higher intensity/complexity measures, CMS believes that 88334 is very similar in work to 88332 *Pathology consultation during surgery; each additional tissue block with frozen section(s)* and therefore should be valued the same.

In a letter from the College of American Pathologists (CAP), "We take issue with the comparison of the reference code 88332, *Pathology consultation during surgery; each additional tissue block with frozen section(s),* to the new CPT code 88334 as "very similar in work." To equate the work of the 88334, a cytologic examination based on review of cellular material imprinting on a slide where each and all fields are at risk for harboring neoplastic cells which are few, to 88332, frozen section evaluation, is fallacious. If the tumor were identifiable grossly, the specimen would be evaluated by frozen section, which is more easily interpretable by virtue of the architectural arrangement of the cells, which is not present on cytologic review.

CAP believes that additional data or rationale would be necessary to substantiate CMS' claim that the two codes have equivalent work, since those of us who routinely perform both services know that there is increased work mainly vested in the necessity to examine every field under at least 10X magnification, which is not inherent in the frozen section process. This additional work was reflected in the RUC survey data which were internally consistent and showed increases in time as well as intensity and complexity measures over the reference code 88332 which is the code to which CMS chose to crosswalk. Both the RUC and a pre-facilitation committee examined the data and rationale carefully and both concurred with the code valuation without issue." The RUC supports these comments and requests that CMS assign the RUC recommended work value of 0.80 for this service.

Continuous Glucose Monitoring

The RUC recommended a value of 0.85 work RVUs for CPT code 95251 *Ambulatory continuous glucose monitoring of interstital tissue fluid via a subcutaneous sensor for up to 72 hours; physician interpretation and report.* CMS has disagreed with this value citing that an appropriate reference service for this new procedure is 93268 *Patient demand single or multiple event recording with presymptom memory loop, 24-hour attended monitoring, per 30 day period of time; includes transmission, physician review and interpretation* (Work RVU=0.52). Therefore, CMS assigned a work relative value of 0.52 to 95251. The RUC respectfully disagrees with this identified reference service and reiterates its previous rationale for the value of 0.85. The RUC carefully reviewed the survey data for this service. The reference service selected by the surveyees was 99214 *Office or other outpatient visit for the evaluation and management of an established patient, which requires 2 of 3 key components: a detailed history; a detailed*

examination; medical decision making of moderate complexity. Physicians typically spend 25 minutes face-to-face with the patient and/or family (Work RVU=1.09). When comparing the reference code to the surveyed code, the RUC noted that although the surveyed codes required greater intensity, technical skill and mental judgement than the reference code, the reference code had 8 minutes more total time than the surveyed code. Therefore the RUC supported the specialty society's recommendation of the 25th percentile of their survey, 0.85 work RVUs.

In addition to the survey support, the RUC supports the American Association of Clinical Endocrinologists comments regarding the comparison of CPT code 95251 to CPT code 93268. They are as follows, "Although the time period associated with cardiac event recording (CPT code 93268) is 30 days, the amount and complexity of data that needs to be reviewed for ambulatory continuous glucose monitoring (CPT code 95251) is considerably greater. As noted in the RUC's recommendations, ambulatory continuous glucose monitoring requires approximately 30 minutes of physician time, including interpretation of over 900 glucose values, overlaid with a patient log of several variables (caloric intake, physical activity, symptoms of hypo- or hyper-glycemia, and other sympotms as they occur). Thus contiuous glucose monitoring interpretation is a four-dimensional analysis as opposed to a two dimensional analysis with CPT code 93268."

Considering all of the aforementioned arguments, we urge CMS to reconsider its decision concerning CPT 95251 and to assign the RUC recommended work value of 0.85 for this service.

Request for Change in Medicare Coverage Decision

CMS has indicated various coverage decisions in its *Final Rule*. The RUC would like to comment on the coverage decision pertaining to Education and Training for Patient Self-Management (CPT codes 98960, 98961 and 98962).

Education and Training for Patient Self-Management

The RUC has made several recommendations for three new CPT 2006 codes 98960, 98961 and 98962 which are timed codes describing education and training for patient self-management services prescribed by a physician and provided by a qualified non-physician health professional using a standardized curriculum. CMS has decided the these new codes are not covered by Medicare. However, CMS does not support this determination with any rationale. The RUC spent a great deal of time reviewing the survey data presented by the American Association of Clinical Endocrinologists (AACE) and American Dietetic Association (ADA). The RUC supports the following comments from AACE, "AACE questions this coverage determination and would like to note that these services would seem to fit into the Medicare statutory benefit category of 'incident to' services. Also, there should be no question about the clinical value of these services for patients with conditions such as diabetes and asthma where education and training have been demonstrated as contributing to improved health outcomes and where such services have been incorporated into naturally recognized clinical practice guidelines, including some developed and disseminated by the National Institutes of Health.

Furthermore, these codes will improve access to proper medical care and prevent delayed disease complications. CMS already supports G0108 and G0109 codes and these codes extend that principle of providing and documenting nationally approved curricula for the improvement of our patients' health."

These services can be potentially used by a host of specialty societies including allergists, immunologists and pulmonologists who have also expressed concern about this non-coverage decision. A letter from the Joint Council of Allergy, Asthma and Immunology states, "These codes clearly come within the definition of a service "furnished as an incident to a physician's professional service" as defined in Section 1861(s)(2)(A) of the Act and consequently are covered under Medicare Part B. Further, there is nothing in section 1862 of the Act which would exclude them from coverage.

Coverage of these codes is critical to the delivery of optimal and cost-effective asthma care. Allergists treat a significant number of patients with asthma. Part of an effective treatment plan includes instructing the patient in self-management including medication management, exercise and environmental controls. In fact, the National Asthma Education and Prevention Program coordinated by the National Heart Lung and Blood Institute (NHLBI) of the National Institutes of Health, in its Expert Panel Report 2, *Guidelines for the Diagnosis and Management of Asthma,* includes patient education as one of its four disease-management strategies necessary to keep asthma under control and improve the quality of life for people with the disease. See http://www.nhlbi.nih.gov/guidelines/asthma/asthgdln.pdf. Further the efficacy of patient education in controlling and preventing asthma is well documented in the medical literature. [1]

In addition, timely and appropriate asthma education as been shown to prevent hospital admissions, reduce the number of outpatient visits, and reduce overall health care costs.[2] In one study, participation in an education program reduced hospitalizations by 60% and saved $6,462 per patient. [3] In another study involving children, education to improve asthma management reduced hospitalizations and save $11.22 for every $1.00 spent. [4]

Given our current focus on quality and the practice of cost-effective medicine, it does not make sense for CMS to deny coverage for asthma education.

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[1] See, for example, Cote J, Cartier A, et.al., Influence of asthma education on asthma severity, quality of life and environmental control. Canadian Respiratory Journal 2000 7:5; 395-400; Clark N, Partridge M. Strengthening Asthma Education to Enhance Disease Control. Chest 2002; 121; 161-1669.

[2] Castro M, Zimmermann NA, Crocker S, Bradley J, Leven C, Schechtman KB. Asthma intervention program prevents readmissions in high healthcare users. Am J Respir Crit Care Med 2003 November; 168: 1095-99; George MR, O'Dowd LC, Martin I, Lindell KO, Whitney F, Jones M, Ramondo T, Walsh L, Grissinger J, Hansen-Flaschen J, Panettieri RA Jr. A comprehensive educational program improves clinical outcome measures in inner-city patients with asthma. Arch Intern Med 1999 Aug 9 23; 159(15): 1710-6. Gibson PG, Coughlan J, Wilson AJ, Abramson M, Bauman A, Hensley MJ, Walters EH. Self-management education and regular practitioner review for adults with asthma. Cochrane Database Syst Rev 2000; (2): CD001117; Mayo PH, Richman J, Harris HW. Results of a program to reduce admissions for adult asthma. *Ann Intern Med* 1990 Jun 1; 112(11): 864-71.

[3] Zimmermann, note 2.

[4] Clark, note 2.

In summary, we believe patient education and training for self-management is a service covered by Medicare Part B and therefore should be paid under the Physician Fee Schedule. Further, coverage of these services will, as demonstrated above, improve care for Medicare beneficiaries and reduce costs to the Medicare program." The RUC supports these sentiments and urges CMS to reconsider its action of not covering these services through Medicare.

Publishing Relative Value Units (RVUs) for All Codes Regardless of Coverage Policy

The RUC is concerned with CMS' recent actions regarding the following services with CPT codes approved in 2004/2005 for inclusion in 2006 CPT that are not covered or not recognized by Medicare: Intracranial Angioplasty and Stenting (CPT codes 61630, 61635, 61640, 61641, 61642), Education and Training for Patient Self Management (CPT codes 98960, 98961 and 98962) and Auditory Rehabilitation Assessment (CPT codes 92630 and 92633). In addition, to these three issues, CMS has not acknowledged the RUC recommendations made for Care Plan Oversight (CPT codes 99339 and 99340). The RUC is also concerned that certain codes remain carrier priced even though RUC recommendations have been submitted for these services, e.g. PET procedures such as 78811 *Tumor imaging, position emission tomography (PET); limited area (e.g., chest, head/neck)*. The RUC spent a great deal of time assessing the data for all of these services and CMS has determined that it will not publish relative values for these services, which other payors and physicians utilize. The RUC urges CMS to reconsider any such action for the following reasons:

- The Medicare RBRVS is now widely utilized by private payors, Medicaid, and workers compensation plans to determine physician payment. CMS must realize that it has broader responsibility for the RBRVS beyond Medicare physician payment.

- Physician group practices may utilize physician work relative values to determine compensation plans and/or to utilize as a benchmarking tool. Physician services may be frequently performed by certain specialties, such as neurosurgery and pulmonologists, while not commonly provided to Medicare patients. It is unfair to create a new inconvenience to these specialties, either for these compensation tools or for non-Medicare payment mentioned above.

- The RUC vigorously reviews each coding issue and does not treat issues that are Medicare non-covered in any other manner than it reviews covered services. In fact, the RUC may not even be aware at the time it reviews a code what the Medicare coverage policy will be.

- In a Practicing Physicians Advisory Council discussion in December 2005, William Rogers, M.D., FACEP, Senior Advisor of CMS, acknowledged that these values should indeed be published.

- The RUC cannot independently publish its relative value recommendations without prior publication by CMS. It is critical that as organized medicine provides

recommendations to CMS that it publish these recommendations in the *Final Rule* each year. These recommendations are typically published in a table entitled "AMA RUC and HCPAC recommendations and CMS Decisions for New and Revised {Year} CPT Codes."

Practice Expense Relative Values

The RUC is pleased that CMS has accepted the RUC recommendations for direct practice expense inputs for the 2006 new and revised codes. The RUC appreciated the acceptance of refinements to the direct practice expense inputs for more than 6,500 existing CPT codes developed through the efforts of the RUC's Practice Expense Advisory Committee and the Practice Expense Review Committee. We understand, however, that you have not implemented this data. We urge you to implement the final practice expense direct inputs by January 1, 2007.

Payment for Splint and Cast Supplies

Since 2000, CMS has excluded cast and splint supplies from the practice expense database for the Current Procedural Terminology (CPT) codes for fracture management and cast/strapping application procedures, since these supplies could otherwise be separately billed using Healthcare Common Procedure Coding System (HCPCS) codes Q4001 through Q4051. CMS proposes to eliminate the separate HCPCS codes for these casting supplies and to again include these supplies in the practice expense database. By bundling the cost of the cast and splint supplies into the practice expense component of the applicable procedure codes under the fee schedule, physicians will no longer need to bill Q-codes in addition to the procedure codes to be paid for these materials. This change would affect the practice expense RVUs for the following CPT codes: 23500 through 23680, 24500 through 24685, 25500 through 25695, 26600 through 26785, 27500 through 27566, 27750 through 27848, 28400 through 28675, and 29000 through 29750.

We appreciate that this proposal makes coding and billing for fracture management and casting/strapping easier by reducing the number of codes that physicians must submit in such situations. We also appreciate that CMS has invited the relevant medical specialties to review direct practice expense inputs for the codes in question and provide CMS with feedback regarding the appropriateness of the type and amount of casting and splinting supplies and about the amount of casting supplies needed for the 10-day and 90-day global procedures. We are interested in reviewing this data, so the resulting inputs enjoy the same level of scrutiny and cross-specialty refinement that all of the other direct practice expense inputs have.

Professional Liability Insurance (PLI) Relative Values - Dominant Specialty for Low Volume Codes

On September 28, 2005, The RUC sent its comments on the *Proposed Rule* published in the August 8, 2005 *Federal Register* regarding our recommendations on improvements to the methodology to calculate Professional Liability Insurance (PLI) relative values. At

this time, the RUC would like to thank CMS for implementing the following new policies:

- *Five Percent Specialty Threshold*: CMS has accepted the RUC's recommendation to remove specialties from the PLI methodology if the specialties represent less than a 5% threshold of the utilization of a particular service

- *Cardiac Catheterization and Angioplasty Exception*: CMS, supported by the RUC, has corrected an ACC clerical error, which resulted in the omission of several cardiac catheterization and angioplasty codes from an exception list, where the risk factor should be "surgical" versus "non-surgical" procedures. In addition, CMS has added the following codes to the existing exception list: 92975, 92980-92998 and 93618-93641.

- *Specialty Crosswalk Issues*: CMS has accepted the RUC's recommendation that the following Health Care Professionals Advisory Committee (HCPAC) professions risk factors should be set to 1.00 as conventional wisdom suggests that their PLI premium data is not greater than $6,152 per year: Clinical Psychologist, Licensed Clinical Social Worker, Occupational Therapist, Psychologist, Optician, Optometry, Chiropractic, Physical Therapist

However, The HCPAC agreed that these professions should review the current available data on their PLI premium data and report back to the HCPAC at their September 29 meeting. In the October 6, 2005 letter from the HCPAC to CMS, the HCPAC recommended more specific PLI data to be utilized in the CMS' PLI methodology. The RUC urges CMS to consider and utilize this more specific data as provided by the HCPAC. This letter has been attached for your continued review.

In addition, the RUC would like to comment on its recommendation to CMS regarding dominant specialty for low volume codes. After an exhaustive review of 1,844 codes with utilization less than 100 Medicare claims per year, the RUC forwarded a suggested dominant specialty for each of these low volume codes to CMS and suggested the use of this list as a substitution for claims data. CMS has indicated that in most cases, the dominant specialty suggested by the RUC is reflected as the specialty with the highest utilization in the most recent dataset. This may be true, as these errors in claims will impact low volume codes differently each year. Our point is that CMS should not rely on claims data to determine the appropriate PLI specialty risk factor for these very low volume codes, but instead use the list as developed by the RUC.

The selection of the appropriate specialty may have a significant effect, particularly for those specialties with high PLI premiums. The following is an example of this impact:

	Specialty in Medicare Utilization	Work	PE	PLI
61705	Neurosurgery	36.15	19.25	8.76
61708	Diagnostic Radiology	35.25	15.15	2.49

In this case, staff predicted that neurosurgery should be the specialty for this entire family of services 61705, 61708, and 61710. The only way to safeguard these low volume services from this type of error caused by claims data is to assign the specialty for these codes and avoid any year-to-year fluctuations.

We submit the attached list of recommended specialties for low volume codes again and urge its use for establishing PLI relative values for 2007.

As always, the RUC appreciates the opportunity to offer these comments to CMS. We look forward to the work ahead in 2006 to further improve the RBRVS.

Sincerely,

William L. Rich, III, MD, FACS

cc: RUC participants